



9110-04-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

46 CFR Part 10

[Docket No. USCG-2016-0029]

Change-2 to Navigation and Vessel Inspection Circular 04-08: Medical Certification Standards, Medications, and Medical Review Process

AGENCY: Coast Guard, DHS.

ACTION: Notice of policy; availability.

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SUMMARY: The Coast Guard announces the availability of Change-2 to Navigation and Vessel Inspection Circular (NVIC) 04-08, "Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials" (NVIC 04-08). Change-2 to NVIC 04-08 contains revisions to Enclosure (1) Medical Certification Standards, Enclosure (4) Medications, and Enclosure (6) Medical Review Process. The revisions to Enclosures (1) and (6) reflect process and procedural changes related to centralization of the evaluation of credential applications at the National Maritime Center and implementation of the final rule that aligned Coast Guard regulations with amendments to the International Convention on Standards of Training, Certification and Watchkeeping

for Seafarers and made changes to national endorsements. The revisions to Enclosure (4) provide more detailed guidance on medications that are subject to further review, and address comments received in response to a notice published in the Federal Register on January 28, 2015 seeking input from the public on this issue.

DATES: Change-2 to NVIC 04-08 is in effect on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit comments online at <http://www.regulations.gov> in accordance with Web site instructions.

FOR FURTHER INFORMATION CONTACT: If you have questions on this document, call or e-mail LCDR Ian Bird, Office of Commercial Vessel Compliance (CG-CVC), 202-372-1255, e-mail [MMCPolicy@uscg.mil](mailto:MMCPolicy@uscg.mil).

#### SUPPLEMENTARY INFORMATION:

##### Viewing Documents

Navigation and Vessel Inspection Circular (NVIC) 04-08 is available on the Internet at:

<http://www.uscg.mil/hq/cg5/nvic/pdf/2008/NVIC%2004-08%20CH%201%20with%20Enclosures%2020130607.pdf>. It can also be viewed on the Coast Guard's Web site at: [www.uscg.mil/nmc](http://www.uscg.mil/nmc).

##### Background

Coast Guard regulations contained in 46 CFR part 10, subpart C, contain the medical and physical standards that merchant mariner applicants must meet prior to being issued a merchant mariner medical certificate. NVIC 04-08 provides guidance to the regulated community on how to comply with the regulations pertaining to medical and physical qualifications for merchant mariners.

On December 24, 2013, the Coast Guard published a final rule in the Federal Register (78 FR 77796) entitled "Implementation of the Amendments to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, and Changes to National Endorsements." It amended 46 CFR parts 1, 10, 11, 12, 13, and 15 to implement the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978 (STCW Convention), including the 2010 amendments to the STCW Convention, and the Seafarers' Training, Certification and Watchkeeping Code, as well as updating requirements for national endorsements. The final rule also established the merchant mariner medical certificate as a document issued independently of the merchant mariner credential. Merchant mariner credentials issued after January 24, 2014, and that require a general medical examination are not valid for service unless

accompanied by a valid medical certificate. Enclosures (1) and (6) of NVIC 04-08 required revision to reflect changes implemented with the final rule and a reorganization of the mariner credentialing function.

Guidance on medication use contained in Enclosure (4) to NVIC 04-08 prior to Change-2 noted that use of certain medications was considered disqualifying for issuance of credentials. The guidance did not provide details on the types of medications that might lead to denial of a medical certificate, nor did it provide discussion of the information and criteria that the Coast Guard considers in determining whether to issue a waiver for certain medications.

In developing this policy, the Coast Guard sought recommendations from the Merchant Mariner Medical Advisory Committee (MEDMAC) on waiver considerations for mariner applicants whose conditions require the use of potentially impairing medications while operating under the authority of the credential. In response to Coast Guard Task Statement 14-09, Medical Evaluation of Merchant Mariners Treated with Potentially Impairing Medications, MEDMAC recommended that medications with central nervous depressant effects, such as opioid, benzodiazepine, or non-benzodiazepine medications, be considered disqualifying and

generally not waivable. They also recommended that the following medications be determined disqualifying: medications that impair vision, anticoagulants, anti-metabolites and cancer treatments, sedating anti-histamines, antipsychotics, opioid-like analgesics, anti-seizure medications, and stimulant medications, such as amphetamine and methylphenidate. MEDMAC's recommendations did not include specific criteria for waiver consideration for mariners whose conditions require the use of potentially impairing medication while operating under the authority of the credential.

On January 28, 2015, the Coast Guard published a notice in the Federal Register requesting public comments on a proposed revision to Enclosure (4) that would provide more in-depth guidance on these issues (80 FR 4582).

We summarize the policy contained in Change-2 to NVIC 04-08 and address the public comments received on the proposed revision to Enclosure (4) below.

### Discussion

*Enclosure (1) and Enclosure (6).* The revised Enclosure (1) *Medical Certification Standards* summarizes the medical and physical requirements for mariner endorsements and provides additional guidance regarding the medical certificate. The revision to Enclosure (6)

provides guidance on the medical review process used to determine if a mariner meets the medical and physical standards for issuance of a medical certificate.

*Enclosure (4) - Medications.* The revision to Enclosure (4) provides guidance to the regulated community on medications that may be deemed disqualifying for issuance of a medical certificate due to risks of impairment or other safety concerns. The new guidance also clarifies the extenuating circumstances related to the use of potentially impairing medications that the Coast Guard weighs in evaluating risks to public and maritime safety, and in determining suitability for a medical waiver. The revised enclosure additionally provides a safety warning to mariners advising them to refrain from operating under the authority of the credential when they are under the influence of any medication that can cause drowsiness, or impair cognitive ability, judgment, or reaction time. The revised guidance for mariners seeking a waiver to use potentially impairing medications while operating under the authority of the credential follows.

#### **I. MEDICATION WAIVERS REQUIRING SPECIAL CONSIDERATION**

Medications that may impair cognitive ability, judgment or reaction time are considered disqualifying for issuance of credentials. The underlying condition, as well

as the effects of the medications, may lead to denial of a medical certificate or may result in issuance of a waiver.

Due to the documented risks of impaired cognition, judgment, and reaction time associated with the use of certain legally prescribed controlled substances; the Coast Guard has determined that use of these medications while acting under the authority of the credential generally will not be waived. These medications include, but are not limited to opioid/opiate medications, benzodiazepine medications, non-benzodiazepine sedative hypnotic medications, and barbiturate medications. However, waivers may be considered, on a case-by-case basis, if the Coast Guard determines that there are exceptional circumstances that warrant consideration for a waiver.

**Exceptional Circumstances.** The criteria for waiver consideration for applicants seeking to use, or be under the influence of, medications that may impair their cognitive ability, judgment, or reaction time, while acting under the authority of the credential, are listed below. Applicants unable to meet all of the criteria are only considered for a waiver under extraordinary circumstances, if the Coast Guard deems the risk of impairment to be sufficiently low. The criteria follow.

1. The mariner was previously granted a waiver allowing use of the same medication while working under the authority of the credential, where the credential was of the same scope of authority.
2. The mariner demonstrated compliance with all terms of the prior waiver.
3. There were no accidents or other safety concerns related to medication, judgment, cognitive ability, or reaction time during the course of the prior waiver period(s).
4. The mariner has been on a stable medication regimen for a minimum of 2 years, as documented by the treating physician and pharmacy records.
  - a. Mariners who have required periodic increases in medication dosing during the preceding 2-year period would not meet this criterion.
  - b. Mariners who have consistently or periodically supplemented their medication regimen with other disqualifying medications during the 2-year period are not likely to be considered as meeting this criterion. For example, an individual who has been on a stable dose of one opioid pain medication for 2 years, but has also periodically taken or filled prescriptions for an opioid cough medication during



that same time period, would not be considered as being on a stable dose of medicine.

c. Mariners whose medication dose has been decreased or tapered off, without subsequent dose increase, may be considered as meeting this criterion.

5. The mariner is not seeking to use, or be under the influence of, more than one medication with risk for impairment while working under the authority of the credential.

6. The mariner's treating physician provides written assessment that adequately addresses all information requested in the section on Recommended Evaluation Data for Medication Waivers Requiring Special Consideration, and that supports a determination that the mariner is at low risk for medication impairment based upon objective testing and standard evaluation tools.

7. When requested, formal neuropsychological/neurocognitive testing, performed as outlined in the section providing guidance on formal neuropsychological/neurocognitive evaluation, documents the absence of significant medication impairment.

8. The mariner does not use any other medications or have any other medical conditions, which may alone, or in combination, adversely affect the mariner's fitness.

9. Use of methadone may not be waived under any circumstances.

The risk presented by the mariner's position may be considered in determining whether to grant a waiver. Because of the wide-range of operational conditions, it is impossible to set out in advance which positions may be suitable for a waiver. The Coast Guard retains final authority for the issuance of waivers. Waivers may include restrictions and/or operational limitations on the credential.

#### **Recommended Evaluation Data for Medication Waivers**

**Requiring Special Consideration.** Applicants seeking consideration for a medication waiver for the use of medications that may impair cognitive ability, judgment, or reaction time, while acting under the authority of the credential, should submit the additional information detailed below, for each medication.

1. A letter from the prescribing and/or treating physician that includes the following:

a. Whether the physician has familiarized himself/herself with the detailed guidelines on

medical conditions and medications contained in NVIC 04-08.

- b. Whether the physician understands the safety-sensitive nature of the credential and the specialized shipboard environment.
- c. A detailed discussion of the condition that requires the use of the potentially impairing medication.
- d. A description of any known complications experienced by the mariner from the use of a particular medication, level of current stability, and prognosis of the underlying condition. The physician should also provide his or her professional opinion on whether the condition is suitable for safety-sensitive work.
- e. A description of the dosage and frequency of use of the medication (this description should be very specific; "as needed" is not sufficient information). The description should also reflect that the physician has reviewed the mariner's pharmacy records for documentation of the number of pills dispensed for use each month and documentation of the length of time that the mariner has been on the medication.

- f. A detailed statement about whether the mariner is taking the medication as directed, and if there are any concerns of misuse or overuse of the medication.
- g. A statement about whether the mariner is compliant with therapy and follow-up appointments.
- h. A statement about whether the mariner requires use of this medication while at work, or while aboard the vessel. If the mariner requires use of the potentially impairing medication while at work or while aboard the vessel, the physician should provide a detailed explanation and rationale for the use.
- i. A statement about whether the physician has advised the mariner of the risks of impairment related to the medication. The physician should also discuss any risks advised, as well as any instructions discussed with the mariner for mitigating risk.
- j. A statement about whether the mariner's other medications, medical conditions, and work/sleep conditions might compound the impairing effects of this medication. This discussion should reflect that the physician has knowledge of the specifics of the mariner's medications, medical conditions, and work/sleep schedule.

- k. A statement about whether the physician has formally evaluated the mariner for the presence of any impairing medication effects. This discussion should include a description of the method of evaluation utilized, as well as the findings.
  - l. A medical opinion of whether the mariner has any medication effects that would impede safe operation of a vessel or interfere with work in a safety sensitive position. This discussion should include the rationale for the physician's opinion.
  - m. A statement of whether the physician has advised the mariner that it is safe to operate a vessel, operate hazardous machinery, and perform safety sensitive functions while under the influence of this medication.
2. When specifically requested by the reviewing authority, additional amplifying information, to include a formal neuropsychological/neurocognitive evaluation.
- a. In particular, mariners seeking waivers to use or be under the influence of potentially impairing opioid/opiate, benzodiazepine, sedative hypnotic, and/or barbiturate medications, while acting under the authority of the credential, may be asked to

submit the results of a formal  
neuropsychological/neurocognitive evaluation.

- b. The Coast Guard will not normally request a  
neuropsychological/neurocognitive evaluation unless  
the applicant meets all other requirements for  
waiver consideration. This is to prevent mariners  
from undergoing costly testing when issuance of a  
waiver is unlikely.
- c. Mariners are advised that submission of  
neuropsychological/neurocognitive evaluation results  
does not guarantee issuance of a waiver.
- d. When a formal neuropsychological/neurocognitive  
evaluation is requested, the assessment should  
include objective assessment of the following  
functions, at a minimum:
  - (1) Alertness, arousal, and vigilance;
  - (2) Attention (focused, shifting, and divided),  
processing speed, and working memory;
  - (3) Reaction time (choice and complex), psychomotor  
function, upper motor speed, and coordination;
  - (4) Sensory perceptual function;
  - (5) Executive function: mental flexibility,  
adaptive problem solving, abstract reasoning,  
impulse control, risk taking/risk assessment,

organizational ability (including visual spatial organization), and planning;

(6) Memory; and

(7) Communication skills.

e. When a formal neuropsychological/neurocognitive evaluation is requested, the evaluation and narrative interpretation must be provided by a neuropsychologist who is board-certified and licensed in the United States.

f. The report of the formal neuropsychological/neurocognitive evaluation should also include:

(1) Documentation of witnessed administration of the medication in question by a licensed medical provider; and

(2) Documentation of the time interval between ingestion of the medication and administration of the neuropsychological/neurocognitive testing battery.

## **II. SAFETY WARNING FOR MARINERS**

Certain medications, whether prescription or over-the-counter, have known impairing effects and their labels warn about the risk of drowsiness and caution against use while driving or operating hazardous machinery.

The nature of shipboard life and shipboard operations is such that mariners may be subject to unexpected or emergency response duties associated with vessel or crew safety, and prevention of pollution and maritime security at any time while aboard a vessel.

In the interest of safety of life and property at sea, the Coast Guard views shipboard life and the attendant shipboard duties that can arise without warning, as safety sensitive duties that are analogous to operating hazardous machinery. As such:

1. Mariners are advised to discuss all medication use with their treating providers and to inform them of the safety sensitive nature of their credential; and
2. Mariners are cautioned against acting under the authority of their credential while under the influence of medications that:
  - a. Can cause drowsiness; or
  - b. Can impair cognitive ability, judgment, or reaction time; or
  - c. Can carry warnings that caution against driving or operating heavy machinery.
3. Mariners are advised that they are considered to be acting under the authority of the credential anytime they are aboard a vessel in a situation to which 46



CFR 5.57(a) applies, even when off-watch or while asleep.

**PUBLIC COMMENTS ON THE PROPOSED REVISION TO THE MEDICATION  
POLICY, ENCLOSURE (4) TO NVIC 04-08**

The Coast Guard's notice sought general comments on whether the proposed revision to Enclosure (4) adequately addresses safety concerns regarding merchant mariners whose medical conditions require use of potentially impairing medication. The Coast Guard received 13 comment letters in response.

The majority of commenters expressed general agreement with the proposed policy clarification, noting that it provides a case-by-case or individualized assessment of a mariner applicant's condition, instead of imposing a blanket denial for all mariner applicants who require the use of potentially impairing medications, while operating under the authority of the credential. The Coast Guard notes that even prior to Change-2, NVIC 04-08 provided for a case-by-case evaluation of each applicant's condition. The additional specificity of the guidance and criteria included in Change-2 will help provide a consistent framework for those evaluations.

One commenter suggested that the guidance in the proposed policy be made enforceable by incorporating it

into regulation. This same commenter also recommended that the guidance include a requirement for mariners to inform vessel owners/operators when they are under the influence of prescription or over-the-counter medications. The Coast Guard disagrees with both comments. First, the purpose of this proposed policy is not to regulate, but instead, to provide guidance to the regulated community on how the Coast Guard evaluates mariners who require the use of certain medications. The policy provides the framework for individualized assessment and allows flexibility for consideration of factors specific to each affected mariner. On the issue of requiring mariners to inform vessel owners/operators about their medications, the Coast Guard does not have any statutory authority to enact such a requirement.

Two commenters disagreed with the policy clarification, arguing that it is overly restrictive in that it presumes that all mariners on the medications are impaired and does not give sufficient deference to the opinion of the treating physician. The Coast Guard notes that the policy is stringent, but holds that it strikes an adequate balance that includes strong consideration of the treating physician's opinion along with objective assessment for signs of impairment. Because of the safety

sensitive nature of the medical certificate, the Coast Guard contends that neither mariner self-assessment, nor provider limited office-based assessment, is sufficient to rule out the risk of significant cognitive impairment in cases where the mariner seeks to use medications with known risk of impairment while operating under the authority of their credential. The Coast Guard notes that this opinion was also shared by all of the medical professionals who provided comment on the policy. They all agreed that the treating provider's office assessment would not be sufficient to ensure that a mariner applicant was free of impairing medication effects when using medications of this type.

Three commenters opposed the proposed policy clarification, arguing that the Coast Guard should never issue waivers for mariners who require the use of potentially impairing medications, while operating under the authority of the credential, regardless of the circumstances. The Coast Guard acknowledges that individuals who use potentially impairing medications may suffer impairment, but finds that there is no evidence to support a conclusion that all individuals will uniformly suffer impairment. On this basis, the Coast Guard disagrees with imposing a new, blanket exclusion against

all mariners who require the use of potentially impairing medication while operating under the authority of the credential. The merchant mariner medical regulations contained in 46 CFR part 10, subpart C, do not prohibit the use of legally prescribed medications, to include opioids, benzodiazepines, and non-benzodiazepine sedative hypnotics; and NVIC 04-08 has always provided for an individualized assessment of mariner applicants.

The Coast Guard additionally emphasizes that the proposed policy clarification is not a change in policy; rather, it provides the regulated community with specificity and outlines the factors that the Coast Guard will consider during the individualized assessment of mariner applicants who require the use of potentially impairing medications, while operating under the authority of the credential. The individualized assessment considers whether the specifics of an applicant's medical condition, medical history, medication use, and cognitive functioning indicate a low likelihood of impairment, or indicate findings that suggest impairment. The Coast Guard contends that the policy clarification contained in Change-2 to NVIC 04-08 adequately strikes a balance between potential safety concerns and putting mariners out of work unnecessarily, and that individuals who meet all of the criteria outlined

in this policy are at low enough risk to warrant consideration for a medical waiver. A blanket exclusion of mariner applicants who meet all of these criteria would likely put mariners out of work without sufficient cause.

One commenter recommended that the Coast Guard provide stronger guidance for over-the-counter anti-motion sickness agents, noting that some of these agents are so sedating that they are sometimes used to induce sleep. The Coast Guard agrees and included a safety warning for use of anti-motion sickness agents that cause drowsiness or impairment.

One commenter argued that the proposed policy clarification's requirement for mariners to report all over-the-counter medications taken is confusing and unnecessarily broad. The commenter noted that while the current medication guidance only requires reporting of over-the-counter medications that were taken for a period of 30 days or more, the proposed guidance suggests that mariners would be held accountable if they did not remember to report even a single dose of a vitamin or fiber tablet taken. The Coast Guard acknowledges that the proposed language on medication disclosure may cause unnecessary concern and confusion. The language in the proposed policy was revised, therefore, to retain the language from the current guidance document regarding the disclosure of over-

the-counter medications. The revised language reads: mariner applicants need only report over-the-counter medications that were taken for a period of 30 days or more, within the 90 days prior to the date that the applicant signs the application to the Coast Guard.

Regarding the use of neuropsychological/neurocognitive evaluation, two commenters asserted that the Coast Guard should require neuropsychological/neurocognitive evaluation for all mariners seeking to use potentially impairing medication, while operating under the authority of the credential. Another commenter agreed that such testing would be useful, but contended that such testing would be time and cost prohibitive. Two commenters opposed requiring neuropsychological/neurocognitive evaluations for all applicants in this category because they deemed it unnecessary and expensive. The Coast Guard agrees that while it might be ideal to review neuropsychological/neurocognitive evaluation results for all mariner applicants who seek to use potentially impairing medications when operating under the authority of the credential, such testing may not be necessary in all cases. Therefore, the Coast Guard has retained the wording from the proposed policy indicating that a neuropsychological/neurocognitive evaluation need only be

provided when requested by the Coast Guard, as part of the individualized assessment.

Another commenter argued that the Coast Guard would not be able to implement a process to request neuropsychological/neurocognitive evaluation on the basis that testing is time-consuming and expensive, and that there are no objective neurocognitive evaluation tools that are readily available to primary care providers. The Coast Guard agrees that neuropsychological/neurocognitive evaluation may be expensive and time consuming and that the associated evaluation tools are not readily available to primary care providers. However, we disagree with the assertion that their use is not warranted in certain situations. Such a situation may occur during the course of conducting an individualized assessment. Without information from a neuropsychological/neurocognitive evaluation, the evaluator is left to presume the presence or absence of medication impairment based upon limited information. To presume that an applicant is impaired by their medication and deny them medical certification when no impairment truly exists, may result in extraordinary costs for the mariner applicant, including loss of employment, with resultant loss of home and healthcare. Alternatively, to assume that no medication impairment

exists when a mariner applicant is actually experiencing impairment, may result in unacceptably high costs to public and maritime safety, should a maritime casualty result. It is important to note that this section of the proposed policy describes the information that the Coast Guard will consider when determining whether extenuating circumstances exist that warrant consideration for a medical waiver for mariners seeking to use potentially impairing medications, while operating under the authority of the credential. As is often the case for any medical condition that is disqualifying and generally not approved for waiver, the evaluation to determine extenuating circumstances may often require assessment and testing that is beyond the scope of the primary care provider. When formal neuropsychological/neurocognitive evaluation is requested as part of the individualized assessment for use of impairing medications, while operating under the authority of the credential, the Coast Guard fully expects that this evaluation will be performed by a specialist trained to perform such evaluations. The Coast Guard also notes that while this testing may be time-consuming and expensive, a formal neuropsychological/neurocognitive evaluation can provide critical documentation on the presence or absence of impairing medication effects for those mariners seeking



to use potentially impairing medication, while operating under the authority of the credential. When the Coast Guard determines that a formal neuropsychological/neurocognitive evaluation is needed, the results of the assessment will be considered in the context of the other extensive medical documentation provided to determine whether extenuating circumstances exist that warrant special consideration for a medical waiver. The decision of whether such testing is too time-consuming or too expensive will ultimately be left up to the individual mariner who seeks to demonstrate extenuating circumstances.

On the question of which neuropsychological/neurocognitive functions should be measured, and the appropriate standard for test outcome, one commenter opined that such a determination would require further substantial research on individual job requirements. Another commenter recommended that the Coast Guard add memory and communication skills to the proposed list of neuropsychological/neurocognitive domains, to make the overall panel similar to that used by the Federal Aviation Administration. Another commenter recommended that a witness observe the mariner applicant taking the medication in question prior to the administration of the neuropsychological/neurocognitive evaluation. The Coast

Guard considered all of these comments and noted that there are already well-established, validated testing measures for various domains of neuropsychological/neurocognitive functioning. Additionally, other modes of transportation have identified specific neuropsychological/neurocognitive domains that are critical for tasks such as flying an airplane or for driving a motor vehicle. The neuropsychological/neurocognitive functions identified for evaluation in the proposed policy reflect those functions recommended as critical for safe motor vehicle driving. In consideration of the public comments, the current policy has been revised to include testing of memory and communication skills as required elements of the neuropsychological/neurocognitive evaluation, when such testing is requested by the Coast Guard. The current policy also specifies that medication administration should be witnessed and documented by a provider prior to the conduct of neuropsychological/neurocognitive evaluation, when such testing is requested by the Coast Guard.

#### Authority

This document is issued under the authority of 5 U.S.C. 552(a), 46 U.S.C 7101 *et seq.*, 46 CFR part 10, subpart C, and Department of Homeland Security Delegation No. 0710.1.

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Director of Inspections & Compliance.  
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